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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BARBEE, MANUEL L

ART UNIT

PAPER NUMBER

2857

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/783,913

Applicant(s)

SCHULZE ET AL.

Examiner

Manuel L. Barbee

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 7-15 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US Patent No. 5,544,661) in view of Brown (US Patent No. 5,997,476).

With regard to a patient worn sensor connected to a patient worn monitoring unit with a processor, as shown in claims 1 and 12, Davis et al. teach a real time ambulatory patient monitor with an ECG sensor and a plethysmograph sensor connected to a portable monitor that includes a microcontroller (col. 2, line 56 - col. 3, line 22; col. 4, lines 22-39; Figure 1, Figure 5, controller 513). With regard to a data acquisition means for receiving information from at least one sensor and logic means for processing the information, as shown in claim 1, Davis et al. teach having data from the ECG and the plethysmograph fed into an analysis logic for analysis (col. 3, lines 1-22). With regard to the monitor having a wireless communication device connected to a first network, a second network and a data archiving and distribution means for communicating with the patient monitor, as shown in claims 1 and 12, Davis et al. teach a cellular phone in the patient monitor communicating with the cellular system, the public switched telephone network (PSTN) and a central monitoring and information management system (col. 3,

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lines 1-22; Figure 1, central station 106, cellular system 104B, PSTN 105). With regard to a terminal means connected to the second network for communicating in a bi-directional manner between a medical care provider and the patient monitor, as shown in claims 1 and 12, Davis et al. teach a clinician that observes data from the patient monitor and communicates with the monitor and the patient (col. 3, lines 15-21; Figure 1, clinician 12). Davis et al. do not teach that either network or the data archiving and distribution means is connected to the Internet or a plurality of patient worn monitoring units or a plurality of medical care provider terminals, as shown in claims 1 and 12.

Brown teaches remote monitoring of the physiological condition of a patient and communicating via the Internet (col. 4, lines 24 - col. 5, line 28). Brown teaches the alternatives of cellular or telephone networks; however, it is well known to the person having ordinary skill that cellular or telephone networks may be used to connect to the Internet. Brown further teaches a plurality of remote patient monitoring units (col. 4, lines 49-63). With regard to a plurality of medical care provider terminals, Brown teaches a workstation that can be a personal computer, remote terminal or web TV connected to the server via the Internet (col. 4, lines 49-63; col. 6, lines 51-62). Since connection to the server is made via the Internet, any connection to the Internet using a web browser is a potential workstation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the patient monitor, as taught by Davis et al., to include communication via the Internet between a plurality of patient monitors and a plurality of workstations, as taught by Brown, because then data

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would have been more accessible on a world wide web server (Brown, column 2, lines 13-50).

With regard to the patient monitoring unit having bi-directional data and voice communication, as stated in claims 2, 3, 7, 13, 14 and 18, Davis teach a the clinician having voice communication with the patient (col. 3, lines 1-22). With regard to the bi-directional data communication comprising instructions to change configurable program instructions, Davis teach that the loading program and setup data to the patient monitor from the central station (col. 5, line 51 - col. 6, line 7, Figure 8, step 802, 803).

With regard to having a microphone and a speaker for the voice communications, as shown in claims 8, 9, 19 and 20, Davis et al. teach a microphone and a speaker (Figure 1, speaker 202B, microphone 202A). With regard to the second network being a PSTN network, as shown in claims 10 and 21, Davis et al. teach a PSTN network (Figure 1, PSTN 105). With regard to the sensor being a biosensor, as shown in claims 11 and 22, Davis et al. teach an ECG sensor and a plethysmograph sensor (Figure 1).

3. Claims 5, 6 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. in view of Brown.

Davis et al. and Brown teach all the limitations of claims 1 and 4 upon which claims 5 and 6 depend and claims 12 and 15 upon which claims 16 and 17 depend. Neither Davis et al. nor Brown teach sending instructions to change alarm limits or data collection parameters for at least one sensor, as shown in claims 5, 6, 16 and 17. The Examiner takes official notice that it is well known to send instructions to a remote monitor to change alarm limits or collection parameters. It would have been obvious to

one of ordinary skill in the art at the time the invention was made to modify the patient monitor combination, as taught by Davis et al. and Brown, to include sending instructions to change alarm limits and data collection parameters, because then the patient monitor would be configured more closely to the needs of a particular patient and dangerous conditions would be caught more quickly.

Response to Arguments

4. Applicant's arguments filed 9 September 2002 have been fully considered but they are not persuasive.

Applicant states that the equivalent to the claimed "medical care provider" in Davis et al. would be the physician, who is not disclosed to interact with the patient using the terminal. Davis et al. teach a clinician that uses the terminal to observe data from the patient monitor and communicate with the patient (col. 3, lines 15-21; Figure 1, clinician 12). The clinician can further notify emergency personnel if necessary to provide medical care (col. 3, lines 22-30). The clinician is also a medical care provider.

Applicant states that Davis et al. teaches away from the claimed decentralized monitoring, because Davis et al. teaches bi-directional voice communication between the patient and clinician at a central station of a single network. Davis et al. teach a different method of communication but does not teach away from the claimed method of communication. Davis et al. teaches a patient monitor that allows the patient to be mobile and reduces the time required for a patient to be hospitalized (col. 1, lines 14-60). While the technology used in the patient monitor taught by Davis et al. may require that the clinician be at a particular location, it certainly does not teach away from the

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improvement offered by using the Internet for communication as taught in Brown. In fact, making data more accessible to the clinician would seem to be a logical step forward. The patient monitor in Davis et al. removes the need for the patient to be in a particular location to be monitored. Communication between the clinician or any qualified medical care provider using the Internet provides the medical care provider with many other options for location in communicating with the patient and makes the information from the monitor more accessible (Brown, col. 2, lines 13-50).

Communication becomes more flexible and convenient for the patient and the medical care provider (Brown, col. 2, lines 13-50), and since the motivation is found in the prior art it is not impermissible hindsight.

Applicant states that both Davis et al. and Brown teach additional layers of abstraction between the patient and the physician. The claims contain no limitations regarding the presence of layers of abstraction.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel L. Barbee whose telephone number is 703-308-0979. The examiner can normally be reached on Monday-Friday from 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on 703-308-1677. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7722 for regular communications and 703-308-7722 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-0976.

mlb
June 10, 2003


MARC S. HOFF
SUPERVISORY PATENT EXAMINER
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